

Lidocaine

Ointment 5%

Composition

Each 1g of Lidocaine ointment contains:

Active ingredient: Lidocaine 50mg

Excipients: Polyethylene glycol, propylene glycol, and purified water.

Properties

Lidocaine ointment is absorbed following application to mucous membranes or damaged skin. It is inactive when applied to intact skin. Absorption occurs most rapidly after intratracheal administration. The onset of action is 3-5 minutes on mucous membrane.

Lidocaine, like other local anaesthetics, causes a reversible blockade of impulse propagation along nerve fibres by preventing the inward movement of sodium ions through the nerve membrane. Local anaesthetics of the amide type are thought to act within the sodium channels of the nerve membrane. Local anaesthetic drugs may also have similar effects on excitable membranes in the brain and myocardium. If excessive amounts of drug reach the systemic circulation rapidly, symptoms and signs of toxicity will appear, emanating from the central nervous and cardiovascular systems.

Central nervous system toxicity usually precedes the cardiovascular effects as it occurs at lower plasma concentration. Direct effects of local anaesthetics on the heart include slow conduction, negative inotropism and eventually cardiac arrest.

Indications

Lidocaine ointment is indicated as topical anaesthesia for:

- temporary relief of pain associated with minor burns and abrasions of the skin, e.g., sunburn, herpes zoster and labialis, pruritus, sore nipples, insect bites.
- anaesthesia of mucous membranes, e.g., various anal conditions such as haemorrhoids and fissures.
- the alleviation of pain during examination and instrumentation e.g., proctoscopy, sigmoidoscopy, cystoscopy, endotracheal intubation.
- dentistry: surface anaesthesia of the gums prior to injection and before deep scaling.

Dosage and method of administration

As with any local anaesthetic, the safety and effectiveness of lidocaine depend on the proper dosage, the correct technique, adequate precautions, and readiness for emergencies.

The following dosage recommendations should be regarded as a guide. The clinician's experience and knowledge of the patient's physical status are of importance in calculating the required dose. The ointment should be applied in a thin layer for adequate control of symptoms. A sterile gauze pad is recommended for application to broken and burned tissue.

Apply 1-2g to tube prior to endotracheal intubation.

In dentistry, apply to previously dried oral mucosa. Allow at least 3-5 minutes for the anaesthesia to become effective.

For sore nipples, apply on a small piece of gauze. The ointment must be washed away before the next feed.

Not more than 20g of the ointment should be administered in any 24-hour period to healthy adults. Debilitated or elderly patients and children over 12 years of age, acutely ill patients, or patients with sepsis should be given doses commensurate with their age, weight and physical condition.

In children less than 12 years of age a single dose should not exceed 0.1g ointment/kg bodyweight (corresponding to 5mg lidocaine/kg bodyweight). Not more than three doses should be administered during 24 hours.

Contraindications

Known history of hypersensitivity to local anaesthetics of the amide type or to other components of the ointment.

Precautions

Excessive dosage of lidocaine or short intervals between doses can result in high plasma levels and serious adverse effects. Patients should be instructed to adhere strictly to the recommended dosage.

The management of serious adverse reactions may require the use of resuscitative equipment oxygen, and other resuscitative drugs (See overdose).

Absorption from wound surfaces and mucous membranes is relatively high, especially in the bronchial tree. **Lidocaine** ointment should be used with caution in patients with traumatized mucosa and/or sepsis in the region of the proposed application.

When **Lidocaine** ointment is used in the mouth or throat area, the patient should be aware that the application of a topical anaesthetic may impair swallowing and thus enhance the danger of aspiration. Numbness of the tongue or buccal mucosa may increase the danger of biting trauma.

Pregnancy and lactation: It is reasonable to assume that a large number of pregnant women and women of child-bearing age have been given lidocaine. No specific disturbances to the reproductive process have so far been reported, e.g. no increased incidence of malformations.

Like other local anaesthetics, lidocaine may enter the mother's milk, but in such small amounts that there is generally no risk of this affecting the neonate.

Effects on ability to drive and use machines: Depending on the dose, local anaesthetics may have a very mild effect on mental function and co-ordination even in the absence of overt CNS toxicity and may temporarily impair locomotion and alertness. With the recommended doses of lidocaine ointment, adverse effects on the CNS are unlikely.

Side Effects

Allergic reactions: Allergic reactions (in the most severe instances anaphylactic shock) to local anaesthetics of the amide type are rare.

Overdosage

Lidocaine can cause acute toxic effect if high systemic levels occur due to fast absorption or overdosage. With the recommended doses of **Lidocaine** ointment, toxic effects have not been reported. Local anaesthetic toxicity is manifested by symptoms of nervous system excitation and, in severe cases, central nervous and cardiovascular depression.

Severe neurological symptoms (convulsions, CNS depression) must be treated symptomatically by respiratory support and the administration of anticonvulsive drugs.

Drug Interactions

With large doses of lidocaine, consideration should be given to the risk of additional systemic toxicity in patients receiving other local anaesthetics or agents structurally related to local anaesthetics, e.g., tlocaine.

Presentation

Lidocaine ointment: Tube containing 15 or 30gm.

* Store at a temperature of 15-25°C.

THIS IS A MEDICAMENT

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of the reach of the children.

Council of Arab Health Ministers,
Union of Arab Pharmacists.

Any information ? Call Our Toll Free No. (971) 800-4994



Produced by: **juphar**
Gulf Pharmaceutical Industries,
Ras Al Khaimah, U. A. E.

